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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GREGORY A. KOPIA, GERALD H. LLANOS,
and ROBERT FALOTICO

Appeal 2008-006026
Application 09/575,480
Technology Center 3700

Decided: May 17, 2010

Before TONI R. SCHEINER, FRANCISCO C. PRATS, and STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method for treating restenosis. The Patent Examiner rejected the claims on the ground of anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

Claims 1, 3, 4, 6, 8 and 9, which are all the pending claims, are on appeal. Claims 1 and 9 are illustrative and read as follows:

1. A method for treating restenosis comprising an intravascular infusion or delivery by release from a surface of a stent of a combination of at least two agents, including an anti-proliferative agent for inhibiting smooth muscle cell growth comprising rapamycin or an analogue thereof and an anti-inflammatory agent for inhibiting smooth muscle growth, both said agents contained in therapeutic dosage amounts.

9. The method of claim 8 wherein the inhibitor of extracellular matrix synthesis comprises halofuginone and the anti-proliferative agent is taken from a group consisting of rapamycin, taxol, or vincristine.

The Examiner rejected the claims as follows:

- claims 1, 3, 4 and 6 under 35 U.S.C. § 102 (a and/or e) as being anticipated by Kamath;[1] and
- claims 8 and 9 under 35 U.S.C. § 103(a) as unpatentable over Kamath and Nagler.[2]

ANTICIPATION and OBVIOUSNESS

The Issue

The Examiner's position is that Kamath described a method of treating restenosis via stent with the anti-proliferative agent TAXOL® and an anti-inflammatory agent. (Ans. 4-5.) The Examiner interpreted the claim term "analogue" to include a compound similar in function to another, relying on the *American Heritage Dictionary*. (*Id.* at 6.) It is undisputed

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[1] Kalpana R. Kamath et al., US 6,335,029 B1, issued Jan. 1, 2002.
[2] Arnon Nagler et al., US 6,159,488, issued Dec. 12, 2000.

that TAXOL® and rapamycin function as anti-proliferative agents. Relying on that functional similarity, the Examiner found that Kamath's TAXOL® is fairly treated as the rapamycin "analogue" recited in the claims, and that Kamath's method of delivering TAXOL® therefore anticipated Appellants' method of delivering an anti-proliferative rapamycin analogue. The obviousness rejection of claim 8 rested on the same interpretation of "analogue."

Appellants contend that treating TAXOL® as a rapamycin analogue is "an improper characterization." (App. Br. 5.) According to Appellants, paclitaxel (the compound in TAXOL®) and rapamycin have different structures and cannot be characterized as "analogues." (*Id.* at 5-6.) Appellants rely on a technical dictionary, and argue that "analogue" in the pharmaceutical sense means "a chemical compound with a structure similar to that of another but differing from it in respect to a certain component." (*Id.* at 7, *citing Dorland's Illustrated Medical Dictionary*.) Appellants contend that under that definition, TAXOL® is not a rapamycin analogue and Kamath did not anticipate the claimed method (*id.*), nor could Kamath and Nagler render the claimed invention obvious (*id.* at 8.)

The controlling issue in this appeal is the proper interpretation of the term "analogue" in the claim phrase "rapamycin or an analogue thereof."

Findings of Fact

1. The Specification states: "[a]ntiproliferative action on SMC *in vitro* has been demonstrated for many of these agents including heparin and heparin conjugates, taxol, tranilast, colchicine, ACE inhibitors, fusion toxins, antisense oligonucleotides, rapamycin an ionizing radiation.

Thus, agents with diverse mechanisms of SMC inhibition may have therapeutic utility in reducing intimal hyperplasia." (Spec. 5:17-21.)

2. The Specification does not use or define the term "analogue," nor did the original claims use it.

3. Kamath described methods for the controlled, localized delivery of bioactive agents to target location within a body. (Kamath, col. 3, ll. 27-29.)

4. Kamath described a method using a stent. (*Id.* at col. 3, ll. 57-67.)

5. Kamath described stent delivery of an anti-proliferative agent such as paclitaxel (commercially available as TAXOL®) in combination with an anti-inflammatory agent. (*Id.* at col. 6, ll. 6-24.)

6. We find that a person of ordinary skill in the art has a medical background.

Principles of Law

> [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997) (emphasis added).

> Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention.

Phillips v. AWH Corp., 415 F.3d 1303, 1318 (Fed. Cir. 2005) (emphasis added).

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (citations omitted).

When determining whether a claim is obvious, an Examiner must make "a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

Analysis

The main issue in this appeal is the proper interpretation of the claim term "analogue." Intrinsic evidence is little help in interpreting the meaning of "analogue" because the word did not appear in the Specification as it was originally filed. Looking to the extrinsic evidence, the Examiner and Appellants provide dueling dictionary definitions, the Examiner's definition referencing only functional similarity, the Appellants' definition referencing structural similarity.

The claim is to be interpreted "as [it] would be understood by one of ordinary skill in the art." *Morris*, 127 F.3d at 1054. We find *Dorland's Illustrated Medical Dictionary* more pertinent to the art than the more general *American Heritage Dictionary*. We find it likely that a person of ordinary skill in this art, having a medical background (FF 6), would interpret a claim to medical treatment in light of how terms are used in the medical field. *See Phillips*, 415 F.3d at 1318. That is, "analogue" of rapamycin means a compound with a structure similar to rapamycin. The

Examiner has not shown that paclitaxel has a structure similar to rapamycin. Accordingly, we will reverse the rejection under § 102. As the rejection of claim 8 under § 103(a) was based on the same claim interpretation, we will reverse it as well.

The method defined by claim 9 includes delivering an "anti-proliferative agent [] taken from a group consisting of rapamycin, taxol, or vincristine." As Kamath taught delivering paclitaxel, commercially available as TAXOL®, the evidence supports the rejection of claim 9 under § 103(a). Appellants' only argument against the rejection of claim 9 is that because Kamath "falls short" as an anticipating reference, it also "falls short" as a § 103 reference. That general argument overlooks claim 9's particular terms.

CONCLUSION

We interpret "analogue" to mean a compound with a structure similar to that of another. Given that interpretation, paclitaxel is not an analogue of rapamycin.

SUMMARY

We reverse the rejection of claims 1, 3, 4 and 6 under 35 U.S.C. § 102 (a and/or e) as being anticipated by Kamath.

We reverse the rejection of claim 8 under 35 U.S.C. § 103(a) as unpatentable over Kamath and Nagler.

We affirm the rejection of claim 9 under 35 U.S.C. § 103(a) as unpatentable over Kamath and Nagler.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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